

**K940737 EDTA GEL (TM)**Jun 3, 1994  
106 days to decisionK940737 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k940737/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received         | Feb 17, 1994                       |
| Decision date         | Jun 3, 1994                        |
| Days to decision      | 106 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Karolinska Institutet</b>                      |
| Location       | Potomac, MD, US                                   |
| Contact        | SVEN LINDSKOG                                     |
| Website        | <a href="http://www.ki.se/">http://www.ki.se/</a> |
| 510(k) history | 1 submissions · 1 cleared · 1994-1994             |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940737/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 3, 2026